

The UK Human Tissue Act and consent: surrendering a fundamental principle to transplantation needs?

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Legislation that authorises controversial organ procurement strategies but ignores respect for autonomy is flawed in principle and predictably unworkable in practice

The UK Human Tissue Act 2004,¹ designed to regulate all activity involving human tissue, organs, or bodies, was introduced in the House of Commons in December 2003, received Royal Assent on 15 November 2004,² and has been partially implemented by Commencement Orders from April 2005. The new act, which repeals and replaces the Human Tissue Act 1961, the Anatomy Act 1984, and the Human Organ Transplants Act 1989, has its origins in events of serious public concern, namely the retained organs scandals at Bristol Royal Infirmary³ and the Royal Liverpool Children's Hospital.⁴ The act is correspondingly dominated by regulation of postmortem examinations and retention of human tissue, with consistent emphasis on the need for fully informed consent. Compliance with these requirements is now mandatory with the threat of up to three years' imprisonment and/or fines for any deviation.

The impact of the original proposals within the bill on research and the clinical practice of pathology have been carefully considered and documented,⁵ with subsequent amendments to ameliorate professional concerns.⁶ The act, however, also carries significant implications for medical practice in areas where donor recruitment for transplantation can take place, and representations on these aspects during readings of the bill⁷ have produced neither clarification, justification, nor amendment within the final legislation.

Section 43 will make it lawful for hospital authorities "to take steps for the purpose of preserving the part for use for transplantation and to retain the body for that purpose". The original explanatory notes for the bill⁸ while it proceeded through parliament implied that such action, prior to consent to transplantation being sought, was then lawful, clause 44 as section 43 then was, merely serving to consolidate this point.

The basis of such an assertion is unclear, but this stance was reiterated by the minister of state before the standing committee, who declared such interventions: "lawful because there is no law against it. ... Just as embalming is lawful, so is cold perfusion."⁹

In section 27 of the act, "Provision with respect to consent", subparagraph 8 states: "a person's relationship shall be left out of account if—(c) having regard to the activity in relation to which consent is sought, it is not reasonably practicable to communicate with him within the time available if consent in relation to the activity is to be acted on". Regardless of the lack of important detail as to which interventions will be accommodated under the above sections, the incompatibility of these declarations with the fundamental principle underpinning the new regulations, that of proper consent, is not addressed, despite interim unequivocal central directives of such a requirement in these fields.⁹

Before the second reading of the bill in parliament on 15 January 2004 there was extensive lobbying by the British Medical Association (BMA) for the bill to go beyond the above "preservation" techniques and base the actual procurement of organs on "presumed consent" (BMA press release, 8 January 2004). This cause was also championed by individual pressure groups (*Today*, Radio 4, BBC December 2004) supported by certain MPs during that second reading,¹⁰ and was the subject of a subsequent private member's bill endorsed by the BMA.¹¹ Despite the stance of the minister of state that "presumed consent" would not be introduced, it is apparent from the above components of the act that "presumption" to some degree is now lawful.

The entire legislation is inevitably a complex balance between respect for the individual and broader societal benefit,

further complicated by an acceptance that the process of consent cannot be rigidly standardised for every scenario and individual. It is reasonable to ask, however, whether the approach taken toward organ procurement in favouring third party benefit and exempting any requirement for informed consent, deviates significantly from other aspects controlled under the act. If this process fulfils the criteria for "presumed consent" the further step from preservation techniques to actual procurement arguably becomes less of an insurmountable hurdle, and it is therefore reasonable to ask whether the persistent call to change the basis of organ procurement toward presumed consent is ethically defensible. The other facet of the legislation worthy of scrutiny relates to the already problematic scenarios in which donor recruitment would take place and lack of specificity as to the manoeuvres which would be accommodated under "preserving the part for use for transplantation".

TAILORING CONSENT TO CIRCUMSTANCE

It could be argued that this is less an issue of "presumed consent" for utilitarian purpose, incompatible with the ethos of the act, and more an aspect where there has to be balancing of the principle of consent with other values as outlined in the explanatory notes.

It should be noted, however, that this principle is directed towards the unpredicted utilisation of material removed as part of a fully consented blood or tissue sample, surgical procedure, or postmortem examination, without having to generate a full list of all potential future tests, which would paralyse the process of consent.

Could the proposals be viewed as equivalent to the powers of the coroner to authorise a postmortem examination without specifically asking for the consent of the next of kin? The differences are both procedural and ethical. It would be unlikely for any postmortem examination to take place prior to making contact with any next of kin; no intervention would take place without the patient being dead by any criteria, and although formal assent will not usually be sought, it is understood that the postmortem examination is necessary for legal purposes and may provide valuable information for the next of kin, rather than being directed toward benefit for a third party.

It could also be argued that there are many occasions in medicine where it is not possible to gain fully informed consent, primarily in emergency settings where the patient is lacking capacity/competence. This activity is, however,

always governed by the principle of the "best interests" of the patient, not some third party.

It has also been argued that transplantation differs from organ retention for education and research in respect of "the very obvious and radical life saving benefits".¹² This would appear to be a tangential line of reasoning, which does not justify abandoning the principle of informed consent and respect for autonomy, but which does define this component of the legislation as "presumed consent" on the grounds that the individual would want to contribute to that societal good. Such a principle warrants evaluation.

"PRESUMED CONSENT"

Although the concept and promotion of "presumed consent"^{13 14} are relatively recent, in reality this approach is no different from the "routine salvaging" originally proposed in the early days of transplantation.¹⁵ Laws of "presumed consent" are referred to,¹⁶ but there is no such presumption within the relevant legislations that accommodate this practice. French law for example simply declares that:

an organ to be used for therapeutic or scientific purposes may be removed from the cadaver of a person who has not during his lifetime made known his refusal of such a procedure.¹⁷

The term "presumed consent" has been described therefore as a fiction: "without the actual consent of the individual, there is no consent",¹⁸ or as "an ill informed notion at best...an outright deception at worst".¹⁹

The key arguments invoked for introducing such "presumed consent" include:

- a. A persistent discrepancy between expression of public willingness to donate and actual formal card carrying or registration²⁰;
- b. the potential for an individual to have his/her wish to donate overruled by the next of kin¹²;
- c. the claimed effectiveness of this strategy in increasing donor numbers in certain European countries,^{21 22} and
- d. the "moral benefit of relieving the grieving relatives of the burden of deciding about donation at a time of great psychological stress".¹³

The first argument is vulnerable on the grounds that individuals may wish to be perceived as altruistic and pragmatic on polling without necessarily

holding those principles or being prepared to take them to their logical conclusion. Opinion polls furthermore do not provide detailed information as to the process of organ retrieval, a factor which may radically influence the result. It is noteworthy that less than 20% of the population are on the donor register,²⁰ a system again characterised by extremely limited information on the process of organ retrieval. The current relatives' refusal rate of up to 58%²³ also provides a more objective marker that there can be no presumption of consent on majority grounds. These considerations generate problems therefore with the argument that it is "reasonable to presume consent" on the grounds that this is "more likely to realise the autonomy of the deceased person".¹²

The second argument of failing to process an individual's wish to donate due to a veto by the next of kin is not evidence based. In considering reasons to agree to a request for organ donation, families can follow three distinct stages of analysis: was the individual a card carrier or registered as a donor; did they ever discuss the issue of organ donation and if so was this in a positive or negative vein, and finally was the individual someone motivated by such a sense of good will to others that they would be likely to accommodate organ donation even without previous discussion? As a clinician practising in intensive care for over 20 years, I have only identified one occasion where a family member overrode an expression of interest via card carrying, namely a father for a son. His argument for refusing the request was that he could not be sure that his son would not have changed his mind about organ donation if he had been aware of the differences of opinion within the medical profession as to the true status of brain stem death that had recently surfaced in the lay press.²⁴ This illustrates the need for full provision of information before any presumption of consent in any format, and given that this currently does not happen, the validity of the second argument is further weakened.

The third argument, as to "efficacy", even if correctly attributed to this measure, is simply a utilitarian excuse for transferring authority and benefit to the broader community at the expense of the individual. All three arguments ignore the risk of organs being removed against a patient or family's wishes if for whatever reason that individual does not register their objection.²⁵ Critics also see a more fundamental conflict with the principle of autonomy and consider any imposed burden to opt out as unlawful,²⁶ it being stated:

The removal of organs without consent would constitute a legal anomaly; we have no legal obligation to rescue, maybe not even a moral one, and to require us to register our refusal to rescue is thought by many to be unreasonably intrusive.²⁷

Presumed consent may furthermore cause such offence among those who hold the tradition of respect for the individual as paramount, only 7% agreeing with the principle of presumed consent in certain surveys,²⁸ that they may record their objections even though they are not opposed to organ donation (Veatch, ¹⁹ p 177).

The fourth and unfashionably paternalistic argument clearly compromises the validity of any consent, in a manner contrary to the ethos of the act and current directives.⁹

The arguments for "presumed consent" are not therefore robust and since public disquiet has led to repeal in other jurisdictions,²⁹ it is difficult to understand the persistent support of professional bodies for this proposal.

MANOEUVRES ACCOMMODATED UNDER THE NEW LEGISLATION

The underlying drivers for section 43 and the aspects of procurement practice that would be facilitated also warrant analysis. As the brain stem dead/beating heart donor population falls because of more effective preventive and treatment strategies, and recruitment is compromised by rising relatives' refusal, there are new initiatives to expand the donor pool. A return to non-heart beating donation³⁰ is a key component of the recent transplant framework³¹ and it is this category of donor that is specifically targeted for procurement measures within the proposed legislation.

There are numerous ethical obstacles to this recruitment strategy, such as difficulty in defining futility, accurately determining the point of death, and considering what can be accommodated under the umbrella of "best interests" when seeking to optimise organ viability, before, during, and after the process of dying.^{32 33} These problems, which are significant even in the "controlled" situation described in the above case study, when the "assent" of the next of kin can be sought and gained prior to any intervention directed toward viable organ retrieval, are compounded in the emergency or "uncontrolled" situation,³⁴ the recruitment scenario specifically targeted within the new legislation. Legitimising, after a potentially arbitrary declaration of death, certain interventions that may include

ventilatory support, mechanical cardiac compression, aortic cannulation, and cold perfusion,³⁵ without addressing these fundamental issues does not make them ethically acceptable and is likely to alienate clinicians in intensive care, coronary care, and accident and emergency departments, the recruitment ground for these donors.³⁶

Since section 43 could also be interpreted as accommodating “elective ventilation”,³⁷ previously declared unlawful,³⁸ the recruitment drive could spread on to acute medical wards where victims of intracranial pathology not considered suitable for escalation of support are cared for.

IMPACT OF THE LEGISLATION AND PROFESSIONAL RESPONSE

It can be argued that the simplistic legitimisation of these interventions under the new law is unlikely to promote their adoption. Predictably, clinicians working in the above already stressful environments would be unwilling to jeopardise relatives’ wellbeing, public confidence, or their own professional reputation by engaging in any activity without the explicit prior consent of the patient or next of kin. Even with such consent, particularly given the reservations as to the validity of the current organ donor card expressed above, clinicians are likely to be wary of the threat to current confidence posed by a conflict of interest, whether real or simply perceived. With additional fundamental problems such as the lack of a uniform definition of death, these concerns would not be eliminated by relying on a separate party, namely the transplant team, to initiate the “preservation” procedures, even if the necessary rapid response could be achieved.

The subsequent incentive to achieve retrieval once the investment in preservation measures has been made, is an aspect also worthy of scrutiny, since coercion is theoretically inherent in discussion with families which is time limited if organ viability is to be maintained. The deployment of trained “facilitators”, based on the US model of procurement,³⁹ would have to be rigorously monitored to ensure provision of all information and prevent any such pressure being exerted.⁴⁰

Further problems include the inherently higher rate of non-viable organs retrieved after such “uncontrolled” recruitment and the negative impact of the final futility of an invasive procedure conducted initially without consent, aside from questions as to whether and how such organs should be reunited with the body. Futility of the undertaking is also inevitable in such “uncontrolled” circumstances simply because

of ignorance of age, comorbidity, or other “social” factors that are subsequently realised on interview with next of kin. This highlights a major flaw in the overall concept of “presumed consent” since the cooperation of the next of kin is required for the screening questionnaire directed at determining contraindications to donation, and this is unlikely to be forthcoming if they are opposed to the process, regardless of any expressed wish on the part of the patient. The end result of non-transplantable organs would also counter the argument used to justify this approach, namely the “very obvious and radical life saving benefits”,¹² which can only be justified if this is genuinely a predictable consequence of the intervention.

Further objections to non-consensual preservation manoeuvres may be raised by families, given the potential of this process to interfere with a determination of the true cause of death. If a proper investigation of a death is compromised, it can be argued that entitlements under the Human Rights Act are correspondingly jeopardised. The interplay between hospital management, individual clinicians, and the coroner in this important area also remains obscure under the new act and warrants clarification. It would be naive for any one party to assume that the other professional groups were working to any template or universally agreed “rules of engagement” and simply fall in line with this.

Given the likelihood of non-compliance by clinical staff on ethical grounds if resolution of these fundamental concerns cannot be achieved, it is noteworthy that the act neither makes mention of conscientious objection nor generates any proposal to address such a response, such as referral to a practitioner prepared to undertake these manoeuvres. This deficiency is compounded by a lack of definition as to where authority would reside in the administrative hierarchy for sanctioning these interventions. It remains to be seen whether individuals would wish to shoulder the responsibility for interventions, which may yet prove to be incompatible with human rights on consent grounds alone, regardless of all the above difficulties.

CONCLUSIONS

In conclusion, there is no doubt that the current imbalance between demand and supply has a significant impact on life and quality of life of those awaiting a transplantable organ.⁴¹ It is questionable, however, whether this justifies the state and its employees overriding respect for autonomy in a manner resembling the practices the new act

seeks to correct. Given the degree of public outrage driving the new regulations, it appears ill advised to compensate for a high refusal rate by legislation that endorses non-consensual interventions, regardless of the hurdles of ethical objections and medical non-compliance.

The only ethically and professionally defensible recruitment strategy for cadaveric donation, in line with the principles deployed in other fields of health care, is to rely on informed and highly specific consent. Such a consent process should provide information on the different scenarios in which organ procurement might take place and the interventions directed toward the goal of optimal organ viability for each of those categories. The individual should then choose to subscribe to any or all of the options. Efforts at increasing donation rates should be directed at engaging the public, possibly through mandated choice,⁴² rather than toward pursuit of “routine salvaging” masquerading as “presumed consent”. It is difficult in today’s climate to understand the persistent calls for “presumed consent”,¹² or indeed the intention under the new act to implement such a strategy, albeit for preservation as a prelude to procurement. The rules of engagement were defined by previous government ministers over a decade ago, before scandal further highlighted the need for information, consent, and respect for autonomy:

We must accept that nobody has a right to anybody else’s organs. If something untoward happens, our organs may be of value to someone else but that should be the result of an altruistic decision about how we want our bodies to be used when we die. It should not be as a result of a right of the recipient...It is the responsibility of the living whose organs may be of use to someone else; it is not anyone else’s job to claim the organs.⁴³

The current acknowledged need for transplantable organs does not change these fundamental principles. Transplantation and the credibility of both the transplant fraternity and broader medical profession can only survive if organ donation in all its permutations represents not “a slight adjustment of the moral focus”,¹² but the fully informed choice of an altruistic public. The Human Tissue Act in its current format appears tangential to this goal. Simplistic legislation that ignores one of the founding ethical principles,⁴⁴ respect for autonomy, is likely to prove unworkable.

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